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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,043	05/21/2002	Jean A. Chmielewski	7040-363	6179

7590 12/29/2004

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EXAMINER

MAIER, LEIGH C

ART UNIT PAPER NUMBER

1623

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,043

Applicant(s)

CHMIELEWSKI ET AL.

Examiner

Leigh C. Maier

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 7-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 11-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/5/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-14 are pending. Claims 7-10 were previously withdrawn as being drawn to a non-elected invention. Claims 1-6 and 11-14 are under examination. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Any objection or rejection not expressly repeated has been withdrawn.

Claim Rejections - 35 USC § 102

Claims 1, 2, 5, 11, and 14 are again rejected under 35 U.S.C. 102(b) as being anticipated by CHEN et al (EP 052413), as set forth in the previous Office action.

Applicant's arguments filed October 12, 2004 have been fully considered but they are not persuasive.

Applicant states that the invention is not limited to cocrystallization of an API with a sugar compound. The examiner can only surmise that Applicant is arguing that the reference does not teach every possible matrix material. The examiner refers Applicant to the election of species requirement.

Applicant further argues that claim 1 "does not recite that the active pharmaceutical ingredient (API) is incorporated into 'a single crystal' is *necessarily* itself a crystal." (emphasis added) The examiner agrees; nor does the claim require that it *not* be a crystal. The claim does not require any particular form, only inclusion.

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Applicant contends “the APIs and biopharmaceuticals are not ‘integral to the crystal’.” However, as Applicant further notes, the claim recites “an active pharmaceutical ingredient . . . included within the crystal.” It is not clear how the API can be included in, but not integral to the crystal.

Applicant states without any evidence that the methods taught in the reference will not produce the claimed product. As discussed in the previous Office action, the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art.

Applicant notes that difference in temperatures used in the processes. However, the reference teaches a saturated solution of the carrier (sucrose). The reference explicitly teaches cocrystallization. Therefore, the reference presents a *prima facie* case for inherency.

Applicant contends that the temperatures used are known in the art to destabilize any APIs and most biopharmaceuticals, yet the reference expressly teaches their use.

Applicant notes that the reference “does not proffer any quantitative data showing exactly how active these enzymes are nor does it show any figures indicating that the enzymes are orientated in the growth-sector specific portion of a crystal.” First of all, there is no particular requirement for activity. Further, the examiner agrees that the reference is silent regarding the orientation of the API in the crystal. However, based on the teaching, there appears to be a reasonable likelihood that the method of the reference produces that claimed product, but the examiner cannot prepare the product, and Applicant has provided no evidence to demonstrate that the reference does not produce the product.

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Applicant goes on to discuss how the methods differ, concluding that the products must be different. It is well known that many products may be obtained in a variety of methods.

Claim Rejections - 35 USC § 103

Claims 1-6 and 11-14 are again rejected under 35 U.S.C. 103(a) as being unpatentable over CHEN et al (EP 052413), as set forth in the previous Office action.

Applicant's arguments filed October 12, 2004 have been fully considered but they are not persuasive. Applicant presents no new arguments not addressed above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Allowable Subject Matter

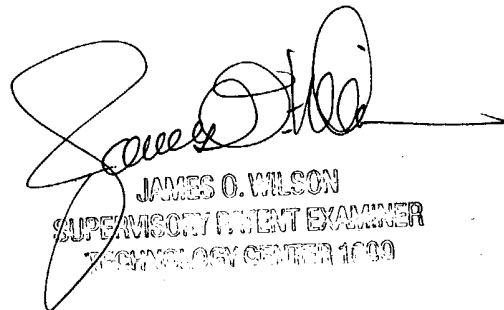
The claims, limited to the use of the elected species, lactose, appear to be free of the art, as set forth in the previous Office action.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Wednesday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.



JAMES O. WILSON
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TECHNOLOGY CENTER 1600

Leigh C. Maier
Patent Examiner
December 22, 2004